

April 16, 2001

Public Information and Records Integrity Branch (PIRIB)
Information Resources and Services Division (7502C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Ariel Rios Bldg.
1200 Pennsylvania Ave. NW
Washington, D.C. 20460

Dear Sir/Madam:

<p>Subject: Docket Control No. OPP-34237 – Response to Request for Comments: Preliminary Human Health Risk Assessment for Atrazine in Support of the Reregistration, Tolerance Reassessment, and Special Review</p>

In response to the subject notice, dated January 14, 2001, Syngenta Crop Protection, Inc. is pleased to have an opportunity to provide our comments in the attached documents as part of the interim process used for FQPA tolerance reassessment. The comments being provided include new information and data, re-analysis of previously submitted information, and data additional assessments, notations where Syngenta believes there are errors in the preliminary risk assessment and associated documents, and some commentary on policy issues that affect the risk assessment process. This file is attached electronically in a PDF format and three hard copies will be sent under separate cover.

New Information on Atrazine

Contained in our comments and attached references are significant new information in the areas of toxicology, risk assessment methodology, water monitoring, residue/dietary, worker, and stewardship. This includes the following.

1. A refined dietary assessment for all registered crops supported by Syngenta for reregistration including atrazine, chloroatrazine metabolites and simazine metabolites common to atrazine. A comparison of the agency's assessment and the 2001 Syngenta assessment.

2. A summary and analysis of corn and sorghum residue data in support of a tolerance reduction which will be requested by Syngenta for these commodities.
3. A comparison of historical residue methodology for atrazine analytical enforcement methodology for hydroxy-triazine
4. Information on Use and Usage of atrazine and current agricultural practices.
5. Additional statistical analyses of toxicology endpoints including data from several luteinizing hormone and development studies.
6. Information on the inappropriate use of the FQPA 10X safety factor in revised preliminary assessment.
7. Information on repeat methodology and the inappropriate use of non-repeat methodology for end point selection.
8. A probabilistic assessment of atrazine exposure in drinking water, focusing on those Community Water Systems (CWS) identified by the EPA in a lower-tiered deterministic analysis, targeted for a refined probabilistic assessment. The results of our assessment indicate there are no CWS that have unacceptable margins of exposure. Syngenta will provide an additional assessment using the Calendex and DEEMS assessment process on the 24 CWS targeted for a refined probabilistic assessment to compare to the probabilistic assessment using DISTGEN and DEEMS included in this submission.
9. A report covering a statistically based synoptic ground water study and analysis of several hundred CWS on ground water to better characterize the exposure of parent and chloro-metabolites in these systems.
10. Results of re-sampling of rural wells from the Syngenta groundwater previously identified as having atrazine detections above the current MCL of 3 ppb or total chlorotriazine residues over 12.5 ppb.
11. Time weighted methodology and estimates of potential total chloro-triazine residues in water.
12. Under separate cover, C-D Roms providing reformatted data tables from the Syngenta voluntary monitoring program and the PLEX database (1993-1999), for total chlorotriazine residues and the sum of parent and chloro residues using predictive equations.
13. A technical paper that discusses the potential for ingestion of atrazine residues on treated turf.

14. A technical paper that provides documentation of the fertilizer impregnation process currently used in agriculture.
15. An overview of agricultural stewardship activities focusing on water quality.
16. Information on the inappropriate methodology used in the Hand-to-Mouth Exposure Scenario in Turf.
17. An evaluation of information provided to date on incident reports.
18. Formal data submissions will be filed under separate cover.

Request for Meetings

Syngenta respectfully requests meetings with the appropriate EPA scientists to address the areas of toxicology (study designs for the reproduction and fertility effects studies requested by EPA and a discussion on selection and methodology for short-term exposure toxicity endpoints; water assessment (statistical procedures for the synoptic groundwater CWS study results and risk assessment methodology), ecotoxicity (probabilistic risk assessment and ongoing studies); and label language clarification changes and harmonization. of labels for all end-use products.

Other Matters

As part of our comments, we are providing an updated bibliography of information submitted to the Agency since the initiation of the Special Review process.

If the Agency makes substantial revisions to the revised preliminary RED using information that Syngenta has not had the opportunity to review we respectfully request an additional comment period that is adequate to address the changes. We also reserve the right to comment further on information referenced in the preliminary risk assessment documents but not made available to date.

If there are any questions concerning matters contained in this submission, please do not hesitate to contact either Janis McFarland at (336) 632-2354, or myself at (336) 632-7207.

Sincerely,

Thomas J. Parshley
Senior Regulatory Product Manager
Syngenta Crop Protection, Inc.

Enclosures

Bcc: Janis McFarland
Charles Breckenridge
James Stevens
Tim Pastoor
Dick Feulner
Beth Carroll
Tom Beidler
Sherry Duvall
Andrea Elder w/all attachments
Gene Burnett
Peter Hertl
Dennis Tierney
Richard Ross
Dennis Hackett
Bob Williams
Bill Swain
Arpad Szarka
Leslie Bray
Vince Alventosa
Alan Nadel
Max Cheung
J. Twardowski
J. Shaw
John Abbott
Debbie Stubbs
Greg Watson
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Gary Dickson
Marian Stypa (Syngenta Canada)
Judy Shaw (Syngenta Canada)
Duane Fairbairn (Syngenta Canada)
Alfred Seiler (Syngenta Basle)
T. Parshley RA File (Triazines Special Review-Book 7) w/all attachments
Chron